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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/730,783 | 12/08/2003 | L. Dean Parks | 1238.009 | 4821 |

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MELVIN K. SILVERMAN
500 WEST CYPRESS CREEK ROAD
SUITE 500
FT. LAUDERDALE, FL 33309

| EXAMINER | |
|---|---|
| PERREIRA, MELISSA JEAN | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 10/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/730,783 | PARKS, L. DEAN | |
| | Examiner | Art Unit | |
| | Melissa Perreira | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/07 has been entered.

Claims 1-5,7,9 and 10 are pending in the application.

### *Priority*

Claims 1-5,7,9 and 10 are given a priority date of 12/8/03 as the recitations of "a concentration range from 0.05% to 0.075% (w/v)" or the exclusion of N-methylpyrrolidone and 2-pyrrolidone carriers were not found in the priority documents

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitation of "a concentration range from 0.05% to 0.075% (w/v)" was not found in the specification. The concentration ranges from about 0.05% to about 0.1% and 0.05% to about 8% (w/v) is provided. The exclusion of N-methylpyrrolidone and 2-pyrrolidone carriers was not found in the specification.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5,7,9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the exclusion of N-methylpyrrolidone and 2-pyrrolidone carriers.

4. Claims 1-5,7,9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "a concentration range from 0.05% to t 0.075% (w/v)" was not found in the specification.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5,7,9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komer (US 5,773,422) in view of Evans et al. (EP 0137 627B1).

7. Komer (US 5,773,422) discloses a topical formulation consisting of (0.1-40% w/v) ivermectin and a carrier (abstract; column 3, lines 6-10; examples 1 and 3) where the carrier may be N-methylpyrrolidone or a N-methylpyrrolidone/propylene glycol mixture. The applications of the topical formulation may be via transdermal patches (column 2, lines 55-58). Komer does not disclose the exclusion of N-methylpyrrolidone as a carrier.

8. Evans et al. (EP 0137 627B1) discloses a topical formulation/cream consisting of an avermectin compound, such as ivermectin, and a carrier (which is not N-methylpyrrolidone) having no adverse skin reaction and a long shelf life (p5 lines 12,20 and 30-32; p12, lines 12-18). The formulation/cream of the disclosure may optionally contain other additives, solvents, etc. but allows for the exclusion of such additives (p7, lines 12,19 and 25; p8, line 23). The concentration of the endoparasiticide (i.e. ivermectin) will depend to a large extent on the specific endoparasiticide, animal to be treated and the amount of the composition to be applied (p11, lines 6-21).

9. Applicant asserts that the formulation of Komer includes N-methylpyrrolidone and/or 2-pyrrolidone which is not suitable for treating dermatological conditions as N-methylpyrrolidone and/or 2-pyrrolidone cause itching, redness, scaling, hives, irritation, etc.

10. In combination with the reference of Evans et al., which contains no N-methylpyrrolidone one would have a reasonable expectation of success for generating a transdermal patch consisting of ivermectin and a carrier, such as propylene glycol without the use of N-methylpyrrolidone or additives.

11. At the time of the invention it would have been obvious to one ordinarily skilled in the art to minimize the amount of the carrier N-methylpyrrolidone in the topical formulation of Komer as it is an irritant that causes itching, redness, scaling, hives (as evidenced in the MSDS sheet and applicant's admission, Remarks filed 10/3/07). The exclusion of N-methylpyrrolidone in the carrier formulation would give predictable results as seen in the reference of Evans et al. where the formulation without N-methylpyrrolidone has no adverse skin reactions and a long shelf life.

12. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The intended use of the "dermatological composition for topically treating dermatological conditions" is not afforded any patentable weight. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
October 10, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER